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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,162	02/23/2004	Assaf Govari	BIO-5042	8493

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EXAMINER	
CWERN, JONATHAN	
ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
09/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/785,162	GOVARI ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-21,23,24,35-37,39-42,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-21,23,24,35-37,39-42,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/3/10 has been entered.

The examiner first notes as a point of matter, that in regards to concerns made by applicant's representative in the previous interview in regards to applicant's compact disc submission, that the compact disc containing a video presentation of the invention was received by the examiner and viewed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16, 18-21, and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6 the limitations referring to the end-effector as "adapted to be" coupled to the thumb control causes a

disconnect between the thumb control and the end-effector. The use of “adapted to” language renders it unclear as to whether or not the end-effector is actually coupled to the thumb control. It is suggested to remove the “adapted to” language and to simply recite that the end-effector is coupled to the thumb control. Similar issues arise in claim 12 (regarding a portion of the controls), claim 13 (robot adapted to manipulate a proximal end of the catheter), claim 18 (robot adapted to be coupled to a proximal end of the catheter).

It is also suggested to change “adapted to” language used in regards to the controller or control unit throughout all of the claims to “configured to”. The controller or control should be "configured to” do something, rather than merely being “adapted to”. Language such as adapted to implies that the controller only need be capable of performing the function.

In general, the term “adapted to” is used throughout the claims in many more limitations than listed above by the examiner. It is suggested to modify all of the limitations which include this term or such limitations will not be given patentable weight.

Furthermore, from earlier claims and from applicant’s disclosure, it appears that the controller/control unit is a part of the robot. However, claims 13 and 18 refer to the control unit as a separate element from the robot. It is unclear whether or not the control unit is a part of the robot from these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ben-Haim (US 6083170).

Ben-Haim discloses a self-aligning catheter. Ben-Haim shows a catheter with a position sensor near the distal tip, and a deflection device to deflect the distal tip of the catheter. Signal processing circuitry drives alignment circuitry to transmit steering signals to the deflection device, causing it to deflect the distal tip of the catheter (column 8 ,line 60-column 9, line 60). The deflection device can include mechanical components. The system automatically controls these mechanical elements which deflect the distal tip of the catheter, and as the system functions automatically it can be considered a robot. As the catheter tip can be deflected up and down by the tip deflection mechanism, an additional alignment mechanism is included which can rotate the catheter, and thus the distal tip. Thus the distal tip can be controllably deflectable in no more than two directions for any given rotation of the distal tip (Figure 8, and column 12, lines 40-65). A catheter advance mechanism is also employed to automatically control movement of the catheter in a direction into or out of the body, advancing or withdrawing the catheter(column 13, lines 39-50). This combination of different movement directions allows for movement with six degrees of freedom. The system

further allows for operator interaction, with various user inputs for controlling different functions of the system or for manual control over the steering of the catheter (column 13, lines 50-67).

Ben-Haim (column 1, lines 50-55) also incorporates by reference Galel (US 5492131). Galel discloses a servo-catheter, and shows steering the catheter based on feedback from the position sensor. The catheter is steered by operating two servo motors located at the proximal end of the catheter which actuate a steering mechanism at the distal end (column 4, line 60-column 5, line 8).

It should be noted that in this 102(b) rejection, the examiner interprets independent claims 1 and 7 as an apparatus containing an end-effector and a controller. Limitations regarding the steerable catheter and thumb control are not given patentable weight. Language used such as adapted to requires that the prior art only show that the system be capable of those functions. Thus, the examiner could interpret the steerable catheter of Ben-Haim as the end effector (of which it is known that such a catheter is capable of being coupled to a thumb control) which is controlled to navigate through the patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16, 18-21, 23-24, 35-37, 39-42, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (US 6083170).

Ben-Haim discloses a self-aligning catheter. Ben-Haim shows a catheter with a position sensor near the distal tip, and a deflection device to deflect the distal tip of the catheter. Signal processing circuitry drives alignment circuitry to transmit steering signals to the deflection device, causing it to deflect the distal tip of the catheter (column 8 ,line 60-column 9, line 60). The deflection device can include mechanical components. The system automatically controls these mechanical elements which deflect the distal tip of the catheter, and as the system functions automatically it can be considered a robot. As the catheter tip can be deflected up and down by the tip deflection mechanism, an additional alignment mechanism is included which can rotate the catheter, and thus the distal tip. Thus the distal tip can be controllably deflectable in no more than two directions for any given rotation of the distal tip (Figure 8, and column 12, lines 40-65). A catheter advance mechanism is also employed to automatically

control movement of the catheter in a direction into or out of the body, advancing or withdrawing the catheter(column 13, lines 39-50). This combination of different movement directions allows for movement with six degrees of freedom. The system further allows for operator interaction, with various user inputs for controlling different functions of the system or for manual control over the steering of the catheter (column 13, lines 50-67).

Ben-Haim (column 1, lines 50-55) also incorporates by reference Galel (US 5492131). Galel discloses a servo-catheter, and shows steering the catheter based on feedback from the position sensor. The catheter is steered by operating two servo motors located at the proximal end of the catheter which actuate a steering mechanism at the distal end (column 4, line 60-column 5, line 8).

While Ben-Haim does not explicitly refer to the use of robots, end-effectors, and thumb controls, Ben-Haim does refer to automatic control, and mechanical components which attach to the catheter and cause the distal tip of the catheter to deflect. That is, while Ben-Haim shows other embodiments where the catheter distal tip is deflected by direct electronic automatic control (column 9, lines 55-60), Ben-Haim also shows embodiments such as described above in which intermediate mechanical components are automatically controlled and used to deflect the distal tip of the catheter. Thus, one of ordinary skill in the art, at the time the invention was made that the distal tip of the catheter could be deflected in a number of different ways. Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system to use mechanical parts which operate with controls on the

catheter (such as a thumb control) and driven automatically (by a robot/controller), as an obvious design choice. Furthermore, steerable catheters with thumb controls are well known in the prior art, as indicated in applicant's published specification ([0128]), and thus it would be obvious to use such a steerable catheter in the system of Ben-Haim. That is, one of ordinary skill in the art, could have modified the intermediate mechanical components for deflecting the distal tip of the catheter in Ben-Haim to operate with the well-known steerable catheters with thumb controls, by modifying the mechanical components to operate on those thumb controls to deflect the distal tip.

Furthermore, the use of the different mechanical mechanisms for deflecting the distal tip allow for a wide range of motion of the distal tip, so that it can be navigated within the patient's body or within a narrow channel such as a blood vessel. A variety of techniques are known in the art for controlling this motion, several of which are disclosed by Ben-Haim, and it would be obvious to move the distal tip in the catheter in any manner which would allow for safe navigation to the target through the desired path in the body.

It should be noted that limitations throughout the claims relating to components "adapted to be" performing some function are not given patentable weight, and those components in the prior art need only be capable of performing those functions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is

(571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737